Registration Decision RD2015-10

Sedaxane

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Registration Decision for Sedaxane

Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the *Pest Control Products Act* and Regulations, is granting full registration for the sale and use of Sedaxane Technical, Vibrance 500FS Seed Treatment (containing the technical grade active ingredient sedaxane) and Vibrance XL Seed Treatment (containing the technical grade active ingredients sedaxane, difenconazole and metalaxyl-m) to be used on various crops to control or suppress soil and seed-borne diseases of seedlings and mature plants.

An evaluation of available scientific information found that, under the approved conditions of use, the product has value and does not present an unacceptable risk to human health or the environment.

These products were first proposed for conversion from conditional to full registration in the consultation document[1] Proposed Registration Decision PRD2015-03, *Sedaxane*. This Registration Decision[2] describes this stage of the PMRA's regulatory process for sedaxane and summarizes the Agency's decision, the reasons for it and provides, in Appendix I, a summary of comments received during the consultation process as well as the PMRA response to these comments. This decision is consistent with the proposed registration decision stated in PRD2015-03.

For more details on the information presented in this Registration Decision, please refer to PRD2015-03, which contains a detailed evaluation of the information submitted in support of this registration.

What Does Health Canada Consider When Making a Registration Decision?

The key objective of the *Pest Control Products Act* is to prevent unacceptable risks to people and the environment from the use of pest control products. Health or environmental risk is considered acceptable[3] if there is reasonable certainty that no harm to human health, future generations or the environment will result from use or exposure to the product under its conditions of registration. The Act also requires that products have value[4] when used according to label directions. Conditions of registration may include special precautionary measures on the product label to further reduce risk.

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1 "Consultation statement" as required by subsection 28(2) of the *Pest Control Products Act*.

2 "Decision statement" as required by subsection 28(5) of the *Pest Control Products Act*.

3 "Acceptable risks" as defined by subsection 2(2) of the *Pest Control Products Act*.

4 "Value" as defined by subsection 2(1) of the *Pest Control Products Act* "... the product's actual or potential contribution to pest management, taking into account its conditions or proposed conditions of registration, and includes the product's (*a*) efficacy; (*b*) effect on host organisms in connection with which it is intended to be used; and (*c*) health, safety and environmental benefits and social and economic impact".

To reach its decisions, the PMRA applies modern, rigorous risk-assessment methods and policies. These methods consider the unique characteristics of sensitive subpopulations in humans (for example, children) as well as organisms in the environment (for example, those most sensitive to environmental contaminants). These methods and policies also consider the nature of the effects observed and the uncertainties when predicting the impact of pesticides. For more information on how the PMRA regulates pesticides, the assessment process and risk-reduction programs, please visit the Pesticides and Pest Management portion of Health Canada's website at healthcanada.gc.ca/pmra.

What Is Sedaxane?

Sedaxane is the active ingredient present in the seed treatment products Vibrance 500FS Seed Treatment (containing sedaxane), and Vibrance XL Seed Treatment (containing sedaxane, difenoconazole and metalaxyl-m). Sedaxane is a fungicide with systemic properties, and it inhibits the normal respiration process in target pathogenic fungi. The sedaxane-based products are used on seed from various crops to control or suppress soil and seed-borne diseases of seedlings and mature plants.

Health Considerations

Can Approved Uses of Sedaxane Affect Human Health?

Products containing sedaxane are unlikely to affect your health when used according to label directions.

Potential exposure to sedaxane may occur through the diet (food and water), when handling and applying the product or when entering treated sites. When assessing health risks, two key factors are considered: the levels where no health effects occur and the levels to which people may be exposed. The dose levels used to assess risks are established to protect the most sensitive human population (for example, children and nursing mothers). Only uses for which the exposure is well below levels that cause no effects in animal testing are considered acceptable for registration.

Toxicology studies in laboratory animals describe potential health effects from varying levels of exposure to a chemical and identify the dose where no effects are observed. The health effects noted in animals occur at doses more than 100 times higher (and often much higher) than levels to which humans are normally exposed when pesticide products are used according to label directions.

In laboratory animals, the active ingredient sedaxane and its associated end-use products, Vibrance 500FS Seed Treatment and Vibrance XL Seed Treatment, were of low acute toxicity by the oral, dermal and inhalation routes of exposure. They were minimally irritating to the eyes and non-irritating to the skin, and did not cause allergic skin reactions. Consequently, no hazard signal words are required on the labels.

Health effects in animals given repeated doses of the active ingredient sedaxane included effects on the liver, endocrine organs and circulatory system. Sedaxane did not cause birth defects in animals. When sedaxane was given to pregnant or nursing animals, effects on the developing fetus (a slight increase in abortions) and juvenile animal (decreased spleen weight) were observed at doses that were toxic to the mother, indicating that the young do not appear to be more sensitive to sedaxane than the adult animal. Sedaxane caused functional effects, possibly related to the nervous system, at high doses in rats. There was no evidence that sedaxane damaged genetic material but it did, however, cause liver tumours in mice and liver, and thyroid and uterine tumours in rats. A cancer risk assessment was conducted based on the uterine tumours found in rats as this was protective of the other tumour types.

The risk assessment protects against the effects of sedaxane by ensuring that the level of human exposure is well below the lowest dose at which these effects occurred in animal tests.

Residues in Water and Food

Dietary risks from food and drinking water are not of health concern.

The dietary risk assessment reported in the Evaluation Report ERC2012-01, *Sedaxane* has been updated to support subsequent use expansions of sedaxane and for the revision to the acceptable daily intake.

Aggregate chronic dietary intake estimates (food plus drinking water) revealed that the general population and infants less than one year old, the subpopulation which would ingest the most sedaxane relative to body weight, are expected to be exposed to less than 2% of the acceptable daily intake. Based on these estimates, the chronic (non-cancer) dietary risk from sedaxane is not of health concern for all population subgroups. The lifetime cancer risk was also not of health concern.

Aggregate acute dietary (food plus drinking water) intake estimates for the general population and all population subgroups were less than 2% of the acute reference dose, and are not of health concern. The highest exposed subpopulation was infants (< 1 year old).

The *Food and Drugs Act* prohibits the sale of adulterated food, that is, food containing a pesticide residue that exceeds the established maximum residue limit (MRL). Pesticide MRLs are established for *Food and Drugs Act* purposes through the evaluation of scientific data under the *Pest Control Products Act*. Food containing a pesticide residue that does not exceed the established MRL does not pose an unacceptable health risk.

The final storage stability studies for sedaxane residues on crop and processed commodities submitted are adequate and support the intervals and conditions under which samples from the crop field trial and processing studies were stored. The MRLs established for sedaxane do not need to be revised. Refer to the Maximum Residue Limit Database on the Maximum Residue Limits for Pesticides webpage for a list of the MRLs established for sedaxane.

Occupational Risks From Handling Vibrance 500FS Seed Treatment and Vibrance XL Seed Treatment

Occupational risks are not of concern when Vibrance 500FS Seed Treatment and Vibrance XL Seed Treatment are used according to the registered label directions, which include protective measures.

Workers treating seed with Vibrance 500FS Seed Treatment or Vibrance XL Seed Treatment in commercial seed treatment operations, workers treating seed on-farm and workers planting treated seed can come into direct contact with sedaxane residues on the skin and through inhalation. Therefore, the label specifies that workers treating and handling treated seed must wear the following personal protective equipment. For commercial seed treatment, workers treating, bagging, sewing, stacking, and forklifting treated seed must wear cotton coveralls over a long-sleeved shirt and long pants and chemical-resistant gloves. In addition, workers cleaning commercial seed treatment equipment must wear chemical-resistant coveralls over a long-sleeved shirt and long pants and chemical-resistant gloves. Workers treating on-farm and/or planting treated seed must wear a long-sleeved shirt, long pants and chemical-resistant gloves. For good hygiene purposes, it is also recommended for workers to wear a dust mask approved by the National Institute for Occupational Safety and Health (NIOSH) during all job activities. Closed transfer is required for commercial seed treatment of barley, wheat, oats, rye, triticale, buckwheat, millet (pearl and proso), teosinte and wild rice. Taking into consideration these label statements, the number of applications and the expectation of the exposure period for handlers and workers, the risk to these individuals is not a concern.

For bystanders, exposure is expected to be much less than that for workers and is considered negligible. Therefore, health risks to bystanders are not of concern.

Environmental Considerations

What Happens When Sedaxane Is Introduced Into the Environment?

Sedaxane is not expected to pose unacceptable risks to non-target organisms when used as directed on the label.

When sedaxane is introduced into the environment as a seed treatment it will adsorb to soil or be taken up into growing plants. Based on the physical-chemical properties of sedaxane and environmental fate data, limited movement in soil is expected and leaching into groundwater or runoff into surface water is not predicted. Although birds and mammals may be exposed to sedaxane if they feed on treated seed, a risk assessment has shown that sedaxane poses practically no risk to birds or mammals, even if a high amount of treated seed is ingested. Although sedaxane is moderately to highly toxic to aquatic organisms, when sedaxane is used as a seed treatment, limited exposure to the aquatic environment is expected. Sedaxane is expected to pose negligible risk to bees from contact and oral exposure. Risks to beneficial arthropods are expected to be negligible.

Value Considerations

What Is the Value of Vibrance 500FS Seed Treatment and Vibrance XL Seed Treatment?

Vibrance 500FS Seed Treatment and Vibrance XL Seed Treatment are end-use products that are effective in the control or suppression of seed and soil-borne diseases in crops.

Vibrance 500FS Seed Treatment and Vibrance XL Seed Treatment provide effective solutions to manage commercially important diseases such as rots (seed, root, crown and foot), seedling blights, damping-off, seed-borne septoria, smuts, bunts and take-all. The multiple modes of fungicidal action found in Vibrance XL Seed Treatment provide benefits in terms of disease resistance management along with increased spectrum of disease protection. Moreover, because of recommended tank-mixes on the product labels, these products provide options for simultaneous management of certain insect pests and fungal diseases.

Measures to Minimize Risk

Registered pesticide product labels include specific instructions for use. Directions include risk-reduction measures to protect human and environmental health. These directions are required by law to be followed.

The key risk-reduction measures on the labels of Vibrance 500FS Seed Treatment and Vibrance XL Seed Treatment to address the potential risks identified in this assessment are as follows.

Key Risk-Reduction Measures

Human Health

Because there is a concern with users coming into direct contact with Vibrance 500FS Seed Treatment and Vibrance XL Seed Treatment on the skin or through inhalation of spray mists and dust, the labels specify that workers treating and handling treated seed must wear the following personal protective equipment. For commercial seed treatment, workers treating, bagging, sewing, stacking and forklifting treated seed must wear cotton coveralls over a long-sleeved shirt and long pants and chemical-resistant gloves. In addition, workers cleaning commercial seed treatment equipment must wear chemical-resistant coveralls over a long-sleeved shirt and long pants and chemical-resistant gloves. Workers treating on-farm and/or planting treated seed must wear a long-sleeved shirt, long pants and chemical-resistant gloves. For good hygiene purposes, it is also recommended for workers to wear a NIOSH-approved dust mask during all job activities. Closed transfer is required for commercial seed treatment of barley, wheat, oats, rye, triticale, buckwheat, millet (pearl and proso), teosinte and wild rice.

Other Information

The relevant test data on which the decision is based (as referenced in PRD2015-03) are available for public inspection, upon application, in the PMRA Reading Room (located in Ottawa). For more information, please contact the PMRA Pest Management Information Service by phone (1-800-267-6315) or by e-mail (pmra.infoserv@hc-sc.gc.ca).

Any person may file a notice of objection[5] regarding this registration decision within 60 days from the date of publication of this Registration Decision. For more information regarding the basis for objecting (which must be based on scientific grounds), please refer to the Pesticide and Pest Management section of Health Canada's website (Request a Reconsideration of Decision) or contact the PMRA Pest Management Information Service.

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[5] As per subsection 35(1) of the *Pest Control Products Act*.

Appendix I Comments and Responses

1. It was questioned as to why sedaxane was only now being consulted on if the end-use products, Vibrance 500FS Seed Treatment and Vibrance XL Seed Treatment, had been available for purchase and use in Saskatchewan in 2013 and 2014.

Response

At the time of the original review, PMRA made the decision to grant sedaxane and its associated end-use products conditional registration pending additional information. The Evaluation Report, ERC2012-01, *Sedaxane*, published 2 October 2012, summarized PMRA's risk assessment, regulatory decision and the reasons for it, as well as the additional information required.

Under the Pest Control Product Regulations, the consultation requirements do not apply when a conditional registration is first granted.

The outstanding information has now been received and reviewed by the PMRA. The Proposed Registration Decision PRD2015-03, *Sedaxane* was posted for consultation based on the PMRA's proposed decision to grant full registrations to these pest control products.